

### REMARKS

This is in response to the Office Action of September 21, 2004. In that Office Action, Claims 25-29, 31, 34, and 38-43 were rejected under 35 USC 103(a) as being unpatentable over International Publication WO 96/40857 in view of U.S. Patent No. 6,190,855 to Herman et al.

It is the position of the Patent Office that the primary reference, WO 96/40857 discloses a fluid processing set for use in a photoactivation treatment where the processing set includes a plurality of containers connected together with openable flow paths. The Office notes that the primary reference does not disclose a light impermeable overwrap for the photochemical agent container, and that Herman et al. disclose a system for treating a biological fluid with a container including such a light impermeable overwrap. Furthermore, it is the position of the Office that inasmuch as the components of the primary reference, WO 96/40857, are assembled at some point in the primary reference system and, thus, these components are deemed to be "pre-assembled," as required by the claims of the application. Applicants respectfully note that the claims, as currently amended, would not have been obvious in view of the cited art for at least the following reasons.

Claim 25, as amended, is now directed to a four-container disposable processing set for use in the photoactivation treatment of a biological fluid, for irradiating pathogens from

the biological fluid. As amended, Claim 25 recites a pre-assembled disposable fluid processing set wherein the first container includes the photochemical agent and is adapted for attachment to a source of a biological fluid. A second container is provided downstream of and pre-attached to the first container. The second container serves as the illumination container and is, therefore, made of a material that is substantially translucent to light in the photoactivating wavelength range. The third container of the disposable processing set is downstream of the second container and is attached to the second container. This container includes an adsorbent material for removing excess photochemical agent and by-products of the photoactivation process. Finally, the fourth container of the set is a storage container. It is located downstream of the third container and is pre-attached to the third container. At least the first and second containers and the second and third containers are attached by sealed, but openable flow paths.

In the references relied upon by the Examiner, assembly of the set and in some cases, manual introduction of the photochemical agent at the time of use are required. In that regard, the user is not provided with a system that is "ready to use."

The multi-container processing set of claim 25 provides advantages that are simply not disclosed nor appreciated in any

of the references cited by the Patent Office. While it is true that some of the containers in the prior art references (e.g., WO 96/40857) are at some point in time attached to each other, the containers are not pre-assembled and pre-attached when first provided to the user.

The present invention provides a complete set with all the necessary containers required for the treatment of a biological fluid from the time of transfer of the biological fluid from a biological fluid source to the time of delivery of the biological fluid to the patient. The only connection required is the attachment of the container including the photoactivation agent to the source of the biological fluid. The photoactivation (photochemical) agent is introduced into the illumination container with the biological fluid. All of the remaining containers are pre-attached in the order of the pathogen inactivating process. They can be (and subsequently are) detached, as necessary, during the process, but no separate connection of the containers is required by the user.

Thus, for example, during a treatment with light, the second, third and fourth containers can all remain together, making the origin of and other information about the blood product easier to establish and track. Moreover, the fact that the containers are pre-attached to one another further reduces the chance that the container system and the sterility of the container system will be breached during the joinder of one

container to another container. In short, the disposable processing set of the present invention is provided to the user "ready to use."

Thus, providing a fully pre-attached and pre-assembled system or set specifically avoids the piecemeal construction of the processing system during the course of the treatment. In this sense, the disposable processing system in WO 96/40857 cannot be said to be truly pre-assembled and/or the containers pre-attached, as recited in amended Claim 1. In a further sense, the disposable processing system disclosed in WO 96/40857 is not ready-to-use, as is the disposable processing set recited in Claim 1.

With regard to the purported obviousness of providing such a set, a fully-integrated set of the type recited in amended Claim 25 would not typically lend itself to use with an illuminator (i.e., light box). The problem faced would be how to treat an illumination container with light when the illumination container has other containers pre-attached to it. Most illuminators known in the art at the time of the present invention allowed for treatment of single illumination containers -- not ones that had other processing containers attached to it. With no illuminators that could accommodate an integrated set, the person of ordinary skill would be led away from such integrated, pre-assembled sets and opt for the piecemeal assembly of the prior art.

In the present invention, at least the second, third and fourth containers remain attached during treatment of the biological fluid in an illuminator of the type disclosed in U.S. Patent No. 6,565,802 and U.S. Patent Application Publication No. US 2003/0035751. This patent and patent application disclose an illuminator with multi-compartments for accommodating the illumination container and the remaining pre-attached containers of a disposable processing system claimed in the present application.

Please note that the patent application that became the '802 patent was previously called to the attention of the Examiner in the 5<sup>th</sup> Supplemental Information Disclosure Statement filed on October 7, 2002. The now issued patent based on this previously cited application and a further continuation application are included in a 6<sup>th</sup> Supplemental Information Disclosure Statement which accompanies this Amendment.

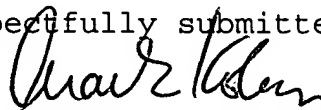
For the record, the accompanying 6<sup>th</sup> Supplemental Information Disclosure Statement also includes U.S. Patent No. 3,211,368, cited by the Examiner in a divisional application claiming priority to the present application (i.e., Serial No. 10/267,566, filed October 2, 2002).

In conclusion, Applicants submit that for the reasons set forth above the pending claims, as amended, are patentable over the art relied upon by the Examiner in the outstanding Office Action, as well as art cited in the accompanying 6<sup>th</sup> Supplemental

Information Disclosure Statement, and previously considered by the Examiner (such as, for example, U.S. Patent No. 5,405,343 to Mohr; U.S. Patent No. 4,938,758 to Al-Sioufi). Simply stated, a pre-assembled, fully integrated disposable processing set that includes the photoactive agent, an illumination container, a container for holding adsorbent material and a storage container wherein at least the second, third and fourth containers remain pre-attached during illumination is not shown or suggested by the art.

Reconsideration and allowance of such claims are respectfully requested.

Respectfully submitted,



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